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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/409,260	09/30/1999	JEFFREY D. SAFFER	01413.0010	5111

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FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/409,260

Applicant(s)

SAFFER ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 05 July 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 8 Sheets 6) ☐ Other: _____

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DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election with traverse of Group III (Claims 14-22; Method for creating high-dimensional vectors by comparing biopolymer information) and Species B (Claims 6, 10, 13, and 19; Biopolymer material is nucleic acid) is acknowledged in Paper No. 9, filed 1 May 2002.

Therefore, claims 1-13 and 18 are withdrawn as not directed to the elected subject matter.

APPLICANTS' ARGUMENTS

Applicants argue that the restriction/election requirement as set forth in Paper No. 4, mailed 14 December 2001, fails to provide support/evidence that "each invention contains divergent subject matter" is found unpersuasive. Applicants are directed to Paper No. 4, mailed 14 December 2001, which provides definitions distinctly separating the inventions into three groups. Again it is acknowledged that the methods are classified within the same class and subclass, however, (the following with emphasis) classification does not exclude such processes from restriction since it is shown that each invention contains divergent subject matter, and are distinctly different processes. Applicants' argument that the species election requirement set forth in Paper No. 4, mailed 14 December 2001, would not constitute a serious search burden is found moot. The species requirement defined the biopolymer materials as differing chemical types (protein, nucleic acid, and other), thus demonstrating that the species are distinct, establishing a separate status in the art, and a different field of search.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 14-17 and 19-22.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 and 19-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 17 (line 2) recites the term “expectancy” which is vague and indefinite. Applicants claim that the “comparing provides results based on an expectancy” (claim 17, lines 1-2), however, it is unclear what applicants’ regard/refer to as “expectancy” to which results are based upon. Applicants can resolve this issue by particularly pointing out the whether the “expectancy” is: 1) A randomly selected value; or 2) A predetermined value; or 3) A value selected based upon some criteria. Clarification is required via clearer claim wording.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 15, and 19-22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Eisen et al. (Cluster analysis and display of genome-wide expression patterns, *Proc. Natl. Acad. Sci. USA*, 1998).

Eisen et al. describes a system of cluster analysis for genome-wide expression data from DNA (nucleic acid; claim 19) microarray hybridization utilizing statistical algorithms to arrange genes according to similarity pattern of gene expression (Abstract). The authors have applied hierarchical cluster analysis to gene expression data, representing relationships among genes by a tree whose branch lengths reflect the degree of similarity between genes (page 14863, Column 2, lines 36-43). The computed trees can then be used to order genes in the original data table, so that genes or groups of genes with similar expression patterns are adjacent (page 14863, Column 2, lines 50-53). Data analyzed was obtained from spotted DNA microarrays and the results placed in a table (square matrix; claim 14); wherein rows represent all genes for which data has been collected, columns representing individual array experiments (claim 15), and each cell representing the measure of fluorescence corresponding to the array (page 14864, Column 1, lines 23-28). A gene similarity metric (high dimensional vector; claim 14) (page 14864, Column 1, lines 39-55) is utilized followed by hierarchical clustering software implemented on a computer (claims 20-22), which computes a dendrogram (distance matrix; claim 14) by assembling all elements into a single tree (page 14864, Columns 1-2, lines 55-62 through 1-11, respectively). The data table is represented graphically (square matrix) each cell is colored based on the measured fluorescence and a dendrogram is appended to the colored table, indicating the relationship among genes (page 14864, Column 2, lines 23-25). Patterns of interest can be readily identified; zooming in on the detailed expression patterns and the genes contributing to these patterns (page 14864, Column 2, lines 52-55). The authors illustrate the application of the described method to data measured from cDNA microarray (8,600 human genes) from a time course of serum stimulation of primary human fibroblasts in a clustered display, wherein each

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gene is represented by a single row of colored boxes and each time point is represented by a single column (Figure 1). Thus, Eisen et al. clearly anticipates the claimed invention.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17 and 19-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Eisen et al. (Cluster analysis and display of genome-wide expression patterns, *Proc. Natl. Acad. Sci. USA*, 1998); taken in view of Altschul et al.

Eisen et al. describes a system of cluster analysis for genome-wide expression data from DNA microarray hybridization (Refer to 102(b) rejection), however, Eisen et al. fails to describe the utilization of a Basic Alignment Search Tool or expectancy to compare biopolymer material (i.e. DNA).

Altschul et al. describes a rapid sequence comparison approach, Basic Alignment Search Tool (BLAST), which directly approximates alignments that optimize a measure of local similarity, the maximal segment pair score (MSP) (Abstract). The method will detect weak but biologically significant sequence similarities (page 404, Column 1, lines 6-9). Alignment scores are expressed as expectancy (MSP) (page 404, Column 1, lines 40-53).

Thus, it would have been obvious to someone of ordinary skill in the art at the time the invention to practice Eisen et al., system of cluster analysis for genome-wide expression data utilizing a cDNA microarray of 8,600 human genes with Altschul et al. Basic Alignment Search

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Tool since Altschul et al. teaches that the Basic Alignment Search Tool can be applied to DNA sequence similarity analysis (Abstract). Further, Eisen et al. states that it may be necessary to find alternative algorithms (i.e. BLAST) and computation methods to bring out inherent structures in the data (i.e. DNA sequence), and to find visual representations that convey the quantitative information effectively (page 14867, Column 2, lines 4-8). Therefore, one of ordinary skill in the art would be motivated to combine a Basic Alignment Search Tool (Altschul et al.) with the teachings of Eisen et al. to bring out the inherent structures in the data (DNA sequence) to correlate sequence similarity with the sequence expression levels (obtained from the microarray experiments) to convey the quantitative information more effectively.

OBJECTION OF DISCLOSURE

The disclosure is objected to because of the following informalities:

The disclosure is objected to because of inadequate figure descriptions on page 8, lines 11-16 (particularly FIG. 4, FIG. 5, and FIG 6). It is acknowledged that the said figures have descriptions, however these descriptions are the same without any distinguishing characteristics. Applicants are required to provide a more adequate brief description of the above figures; i.e. "FIG. 4 is a flow chart of steps of an implementation of a method for creating context vectors for biopolymer material utilizing predefined domains".

The disclosure is objected to because it contains an embedded hyperlinks and/or other forms of browser-executable code and delete them on pages 15 and 18, lines 22 and 15, respectively. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by

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reference. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See M.P.E.P. § 608.01 and § 608.01(p).

The disclosure is objected to because of a blank space on page 22, line 2.

INFORMATION DISCLOSURE STATEMENT

The reference indicated on PTO-1449 (Higgins, Desmond G., "Sequence ordinations: a multivariate analysis approach to analyzing large sequence data sets") was not considered because a reference copy was not included in applicants' IDS. Further, references lined through on page 5 of the Information Disclosure Citation filed 17 April 2002, Paper No. 7, were not considered because the images could not be seen (i.e. completely black). Applicants are invited to submit a new PTO-1449 with a copy of the above references should applicants desire consideration.

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: August 8, 2002

Examiner Initials: *CSM*


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600